K011466

JUN - 6 2001

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510(k) Premarket Notification Summary

Contact:	Jim Mixon
Date:	May 8, 2001
Trade name:	QED diode detectors (model 1112-1116)
Common name:	patient diode detector
Substantial equivalence:	Theta System/Sun Nuclear Isorad diode detectors

Description:

QED detector series consists of five models of detectors for photon and electron beams of different energy ranges. All five models have the same proprietary p type silicon pn junction diode die inside. The diode die is surface-mounted in FR4 glass re-enforced epoxy resin. The die is in the center of the circular area. The die plane is parallel with the area. Buildups with different sizes and/or different materials mounted above the die serve radiation beams with different energy. The bottom of the detectors is flat and the buildup is on the top with hemispherical shape. The detectors are painted on all sides with colors that correspond to the model number and specified energy range.

Intended use:

QED and Isorad detectors are both designed as in-vivo verification tools for the dose delivered to the patient during radiation therapy.

Similarities and differences between QED and Isorad diode detectors:

The overall functionality of QED detectors is the same as the Isorad detectors. QED detectors offer an alternative to the customers for their different packaging shapes.

Similarities:

1. In-vivo verification tools for the dose delivered to the patient during radiation therapy.
2. No external bias voltage applied for the measurement
3. Same coaxial cable and BNC connector
4. Same three energy ranges for photon beams: 1-4 MV, 6-12 MV and 15-25 MV.
5. Same color codes to identify the energy range of the detectors

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Major differences:

1. QED is flat on one side with the internal silicon die parallel to the flat side. Isorad is cylindrical with the die normal to the cylindrical axis.
2. QED has conical symmetry and (normal to the die axis) and is better suited for flat surfaces that are normal to the beam axis. Isorad is a cylinder and is better used for irregular surfaces that are not normal to the beam axis.

Another difference between Isorad and the QED detectors is that the silicon pn junction diode, the active element inside, is changed from n type to p type. The change is to reduce the diode response variation with the dose per pulse and accumulated dose of the radiation beam.

Safety and Effectiveness Summary for QED Diodes

QED diode detectors (Model 1112-1116) are fully grounded and equipped with a 3-meter low noise coaxial cable and a BNC connector. There is no bias voltage applied to the diode when connecting to an electrometer designed for in-vivo dosimetry. Therefore, there is no shock hazard to the patient when using it properly.

Sun Nuclear has deemed the devices safe and effective for their intended uses as long as they are used in accordance with all of the accompanying labeling and instructions. When used and calibrated correctly, QED detectors can detect the discrepancy between the expected radiation dose and the actually delivered dose to the patient. This is crucial to the safety of the patient and the effectiveness of the treatment. Sun Nuclear believes that responsible design and quality assurance practices were followed during the development and manufacture of QED diode detectors (Model 1112-1116).

Safety features of QED diode detectors

Feature	Effect
1. No bias voltage applied	Eliminate electrical shock hazard
2. Coaxial BNC connector	Prevent being connected to a triaxial connector of an electrometer with high voltage
3. Low noise coaxial cable	Provide stable measurement and low leakage
4. Color coding	Provide easy identifications of different energy ranges

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2001

Mr. Jim Mixon
Quality Assurance Manager
Sun Nuclear Corporation
425-A Pineda Court
MELBOURNE FL 32940

Re: K011466
QED DIODE DETECTORS, MODELS 1112-1116
Dated: May 24, 2001
Received: May 29, 2001
Regulatory Class: II
21 CFR 892.5050/Procode: 90 LNH

Dear Mr. Mixon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(K) Number (if known): K011466

Device Name: Sun Nuclear'S QED (Models 1112 – 1116) Diode Detectors

Indications for Use:

Sun Nuclear's QED (Models 1112 – 1116) is a diode detector designed to connect to a diode dosimeter system in order to measure the patient's dose during radiation therapy treatment.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use**_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K011466